

AWARD NUMBER: W81XWH-11-1-0837

TITLE: Assessment of the Ability of the medical health care provider to detect manifestations indicative of TBI and management of care for TBI through the utilization of High Fidelity Simulation.

PRINCIPAL INVESTIGATOR: Dr. Joan Tilghman

CONTRACTING ORGANIZATION: Coppin State University
Baltimore, MD 21216

REPORT DATE: September 2015

TYPE OF REPORT: Addendum to Final

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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REPORT DOCUMENTATION PAGE

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6. AUTHOR(S)

Dr. Joan Tilghman

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5e. TASK NUMBER

5f. WORK UNIT NUMBER

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7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Coppin State University
2500 West North Avenue
Baltimore, MD 21216

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

The longitudinal research study was to consist of two Phases. Phase one (12 months) consisted of an expert Interdisciplinary panel (Registered Nurses, Biologists, chemists, mathematics, neurologist and Simulation expert). This phase included training about TBI for the research team and the development of TBI scenarios for the high fidelity Trauma Simulator, and an educational intervention to evaluate the efficacy of the human simulation training for military medics in battlefield situations. The expert panel in collaboration with the Simulation expert developed TBI battlefield scenarios that were piloted prior to the collection of data from study participants. The training for the medics about assessment and management of TBI based on the educational intervention and simulation training was to be implemented during Phase 2 of the research study. Phase 2 (12 months) of the research study was to collect data about the medics ability to retain and demonstrate acquisition of knowledge and skills to be able to assess manifestations of TBI and identify a plan of care. The data collected would provide information about the medics' efficacy of assessment and management of care for TBI in the battlefield.

15. SUBJECT TERMS

Simulation, high fidelity, longitudinal, TBI, assessment, medic

16. SECURITY CLASSIFICATION OF:

a. REPORT
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b. ABSTRACT
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c. THIS PAGE
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17. LIMITATION OF ABSTRACT

UU

18. NUMBER OF PAGES

13

19a. NAME OF RESPONSIBLE PERSON
USAMRMC

19b. TELEPHONE NUMBER (include area code)

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Introduction

The research was intended to assess the ability of the “medic” (medical health care provider) to detect manifestations indicative of Traumatic Brain Injury (TBI) and identify how to proceed with the management of care for TBI through the utilization of High Fidelity Trauma Simulation. The research project included two phases. Phase one was completed in the First 12 months of the project. Phase One included expert consultants (Neurologist and Simulation expert) to develop the clinical scenarios, educational materials and pilot the scenarios for the research study. Phase Two would include the conducting of research to evaluate the efficacy of the simulation training. The purpose of the training was to provide the military medic with the requisite skills to assess the manifestations of TBI and identify what actions to take for management of TBI, in a mock battlefield setting.

The hypotheses to be tested in the research study were:

Hypothesis 1. The study participants will be able to identify the manifestations for patients with traumatic brain injuries in pre and post evaluation measures.

Hypothesis 2. The study participants will have an increased rate of the identification of initial treatment for patients with traumatic brain injuries in posttest evaluation.

Hypothesis 3: The study participants will have increased scores on the instruments: Satisfaction with Learning and Self-Confidence in Learning.

The research study was officially suspended in December 2012. Coppin State University and the Principal Investigator (PI) acknowledged that Grant Award # W81X -11-1-0837 was on stop payment and that no work was performed during the time the project was on that status. The PI began in November 2012 to seek to have the project funding reinstated. After diligent and persistent attempts by the PI to get the research reinstated a No Cost Extension was awarded Sept. 4, 2014. There were no additional costs to the US Army Medical Research Acquisitions Act associated with the requested NCE. The period of performance for the NCE is was September 30, 2014 – September 30, 2015.

The next phase of the research involved the recruitment of participants. The participants were to be recruited from the Army National Guard. The Army National Guard required a MOU to establish a relationship that would provide permission for the recruitment of participants. The MOU was signed and approved by the authorizing officials at Coppin State University (after a period of 6 months) on June 1, 2015 and then sent to the Army National Guard on June 2, 2015 for the appropriate National Guard signatures. The PI sought to ascertain when the National Guard signatures are obtained. The final portion of the research and the recruitment of participants was to begin upon receipt of the approved MOU with all appropriate signatures. Upon approval of the MOU, we could have proceeded with recruitment of participants for the TBI Project. However the Memorandum of Understanding (MOU) to be used to

recruit participants and obtain National Guard participation was never finalized by the Army National Guard Judge Advocate General's Corp (JAG) Office.

Key Research and Training Accomplishments

- 9/19 and 9/29/2011 Teleconference meetings with consultants. Teleconference meetings with consultants: Dr. Jeffrey Bazarian (Neurologist) and Dr. Linda Spillane (Simulation Expert) to identify relevant TBI content for scenarios.
- Nov. 3, 2011: Orientation for all persons on the research team to Helene Fuld School of Nursing (HFSON) Simulation laboratory. The orientation provided an overview of simulation utilization and demonstration of high fidelity trauma simulation. The trauma simulators is designed to emulate human-like features with trauma indicators which provide an understanding of how to perform patient assessment and provide interventions to patients.
- January 2012: Permission to use research instruments in research obtained from the National League of Nursing. Research instruments: Assessment of knowledge of TBI assessment and treatment and Assessment of Satisfaction with Learning. And Self-Confidence in Learning.
- April 2012: United States Army Head Trauma curriculum used to train military medics obtained from: Sandra M. Escolás, PhD, CIP, LTC, MS. Office of the Dean. Assistant Dean for Research, Human Protections Administrator Army Medical Department Center and School, Fort Sam Houston, Texas 78234. Curriculum used to further develop clinical scenarios and evaluation instrument for medics retention of knowledge.
- May 2012: Spring 2012 Issue Luminaire featured Dr. Tilghman and Research Team. Article titled *"Dr. Joan S. Tilghman, PI to bring simulation Training to Medics"*.
- May- 2012: Meeting to discuss the recruitment of study participants from Army National Guard (ANG) units at Camp Fretterd Military Reservation, Beacham Medical Facility, 5555 Rue Saint Lo Drive, Reisterstown, Maryland, 21136.. Attendees at the meeting: Dr. Tilghman, Major Fox, Deputy Surgeon, ANG and Sergeant First Class Barbour ANG, A presentation of proposed research discussed. A follow up was scheduled for the earliest possible date to meet with the Commanding Officer of the ANG on 7/21/2012.
- June 28, 2012: TBI Team meeting Research Team Workshop Team contributions and resources discussed at workshop. Workshop Objectives- at the end of the workshop the participants will be able to: Demonstrate an understanding of the relevance of training materials for the medics to assess and evaluate TBI; identify the components/materials required/necessary to "set up" a simulation and identify strategies to provide an environment that is suitable and applicable for a clinical scenario
- July 2012: Follow up Meeting with Army National Guard Surgeon General and Commanding Officer (Colonel Bochicchio, Daniel ANG)and with Courville, Faith A Captain ANG This meeting was to present the proposed research and request permission to recruit participants. The meeting included a presentation of the research. The PI was informed that a Memorandum of Understanding (MOU) would be drafted and reviewed by the National Guard attorneys and then the Coppin State University attorney for legal sufficiency.
- Sept. 27, 2012: Neurologist Consultant and Simulation consultant visit for piloting of TBI scenarios and research team training. A workshop was held with the consultants to discuss the training for the research team on simulation. The consultants provided an overview of the TBI case scenarios. Neurology Consultant and Simulation Expert provided training and education for piloting of TBI scenarios. Mock clinical scenarios were conducted with consultant.
- Dec. 2012. Grant funding officially suspended.
- Nov. 2012 – Sept. 2014. Correspondence to have No Cost Extension (NCE) approved began Nov. 2012 and NCE was awarded Sept. 2014.
- Sept. 14, 2014: Grant Award # W81X -11-1-0837 reinstated. The reinstatement allowed the PI to reestablish working on many aspects of the grant that were to be completed and updates as needed. These areas included reestablishing communications with the Army National Guard (for recruitment of participants) and responding to changes in the organization as it relates to "new" contact persons at the Army National Guard. These "new" persons required information and orientation about the TBI research and the arranging for recruitment of participants.

- September 6, 2014- Dec. 2014: Communication with the Army National Guard about the Research study and how best to recruit participants. Review of all documents to be used in the research study is being done. Meetings held with command level officers of the Army National Guard stationed at Camp Fretterd, Reisterstown Maryland to assure there is consensus and understanding about recruitment of participants. Communications ongoing to ensure there is approval among all levels of administration to recruit participants .
- April 2015: Continuing review of documents for “Assessment of the Ability of the Medical Health Care Provider to Detect Manifestations Indicative of TBI and Management of Care for TBI Through the Utilization of High Fidelity Simulation” submitted by Dr. Joan S. Tilghman, to US Army Medical Research and Materiel Command (USAMRMC), Office of Research Protections (ORP), Human Research Protection Office (HRPO).
- April 2015: Coppin State University Institutional Review Board Approval Feb. 13, 2015 for the period of 15 April 2015- 10 April 2016.
- Feb.-May 2015: Review of the Memorandum of Understanding by the Judge Advocate General’s Corp (JAG) Office and Coppin State University authorizing officials.
- June 1, 2015:MOU signatures obtained from Coppin State University authorizing officials
- June 2, 2015: MOU (signed by CSU authorizing officials) sent to the Army National Guard officials for applicable signature.

Reportable Outcomes

- Dr. Joan Tilghman awarded Subcontract. PI at Coppin State University. “Juxtopia® CAMMRAD Platform for Improving Trauma Skills Training” Oct. 2015-Sept. 2017
- Development of simulation scenarios utilizing high fidelity simulation to identify the efficacy of the *medics* ability to assess and manage manifestations of TBI
- Development of Evaluation of Knowledge about the medics efficacy of assessment and management of TBI
- Piloting of mock TBI scenarios by TBI Research Team
- Tilghman Paper Presentation at Faculty Research Conference. Coppin State University, Baltimore Md. March 2012. Interdisciplinary
- Research Team featured in Spring 2012 issue of Luminaire

APPENDIX A

**JUXTOPIA, LLC
SUBGRANT NO. JXTCDMRP15-1
UNDER
U.S. DEPARTMENT OF DEFENSE
OFFICE OF THE CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS
GRANT NO: W81XWH-15-C-0156**

TITLE: Juxtapia® CAMMRAD Platform for Improving Trauma Skills Training

SUBGRANTEE: Coppin State University
Helene Fund School of Nursing
Health and Human Services Building, Suite 431
2500 West North Avenue
Baltimore, MD 21216-3698
EIN:

SUBGRANT PERIOD: October 1, 2015 to September 29, 2017

PREAMBLE

This contract Agreement is between Juxtapia, LLC, herein known as Juxtapia (Corporation), a for profit entity located at the Emerging Technology Centers within Johns Hopkins Eastern facility with an address of 1101 East 33rd Street, Suite #B303, and Coppin State University, herein known as Subgrantee, an institution of higher education organized under the laws of Maryland, located at 2500 West North Avenue, Baltimore, MD 21216-3698. It constitutes a subgrant under grant number **IIP- W81XWH-15-C-0156** (Prime Agreement), which was issued to Juxtapia, LLC by the **Department of Defense (DOD) Office of the Congressionally Directed Medical Research Programs (CDMRP)** on **September 30th, 2015**.

In consideration of the premises and other good and valuable consideration, the receipt and sufficiency of which are acknowledged, and intending to be legally bound, the parties expressly agree to the terms and conditions contained in this Agreement.

ARTICLE I. STATEMENT OF WORK

Both parties intend to cooperate in the performance of this project entitled “Juxtapia® CAMMRAD Platform for Improving Trauma Skills Training” (aka Juxtapia® CAMMRAD Medic) under Juxtapia’s Department of Defense (DOD) Rapid Innovation Fund (RIF) Broad Agency Announcement (BAA) award from the DOD office of the Congressionally Directed Medical Research Programs (CDMRP) referencing OSD-DHP-BAA-RIF-0001-1005 (RIF14005).

ARTICLE II. KEY PERSONNEL

The activities to be performed under this Agreement are under the direction of Dr. Joan Tilghman, Professor of Nursing at the Coppin State University Helene Fuld School of Nursing. The activities to be performed under this Agreement are under the direction of Dr. Joan Tilghman, Professor of Nursing at the Coppin State University Helene Fuld School of Nursing. Should they be unable to continue during the period of performance of this Agreement, Juxtapia reserves the right to approve or disapprove any successor recommended by the Subgrantee.

APPENDIX B SIMULATION SCENARIOS

Development of scenarios :Moderate to Severe TBI

Objectives

At the completion of this exercise, the medic will demonstrate the ability to:

- Perform an initial evaluation of a patient at risk for multiple injuries including head injury. (Primary survey, immediate interventions, secondary survey)
- Identify the patient with a significant head injury
- Calculate a GCS accurately
- Recognize the need for frequent reassessment of neurologic status
- Perform appropriate interventions in the face of a deteriorating mental status (these interventions will depend on what medics are able to do)
- Recognize the need to transfer the patient to a higher level of care

SCENARIO #1

You are on duty and are called to evaluate a soldier who was riding in a jeep that hit an explosive device. Per witnesses to the accident, he was thrown from the vehicle, landing approximately 20 feet away. He was unresponsive at the scene with an obvious deformity to the left arm.

VS : Heart Rate 110, BP 110/76, RR 22

The soldier is covered in dirt; there is a contusion with abrasion to the forehead. He opens his eyes to painful stimuli (eyes = 2); He is disoriented but trying to answer questions (verbal=4); He localizes pain (motor = 5) His pupils are 4 mm, equal and reactive to light.

AVPU (Alert/Verbal/Painful/Unresponsive): Red Flag: • Inability to recognize people, place decreased; call for evacuation.

Primary Survey (Control Hemorrhage, ABCDE):

C: No uncontrolled hemorrhage

A: Protecting airway, confused conversation

B: Equal bilateral breath sounds

C: Peripheral pulses present (and vital signs as above)

D: GCS 11 (red flag • Inability to recognize people, place→call for evacuation) Apply c-collar?

Initial Interventions

IV access

Oxygen

History: Unable to obtain from patient due to his mental status

Secondary Survey:

HEENT Abrasion to forehead; No obvious facial fractures

PERRL; No periorbital trauma

Ears: hemotympanum on right

Clear fluid from left nostril

No dental or intra-oral trauma

Neck Trachea midline, no crepitus

No step-off

Chest

Contusion to anterior chest wall

No obvious deformity

Breath sounds equal

Heart

Tachycardic

Abdomen

No bruising, non-distended, non-tender

Pelvis

Stable

Extremities

Pulses +2 in all extremities

Obvious deformity left forearm

Back

No deformity or step-off

Based on this presentation, the medic should place IV, O₂ (if avail), C-collar, and recommend transfer to a higher level of care. 5 minutes after the secondary survey, the medic is called back to see the patient, who is now unresponsive.

Reassessment

AVPU ; left pupil 6 mm, right pupil 4 mm

No eye opening (1); Withdraws to pain (4); Incomprehensible sounds (2) GCS 7

Maintaining his airway

Respirations irregular and heart rate 56

Peripheral pulses remain +2; BP 160/96

Remainder of exam unchanged

Expected Actions are:

Intubation vs. assisted vent with BVM

Mannitol

Avoid hyperventilation

METI programming

Initial Vital Signs: Heart Rate 110, BP 110/76, RR 22; oxygen saturation 92% if this is available to medics

Eyes – pupils equal, opens eyes to painful stimuli

The initial trauma evaluation including obtaining IV access should take approximately 15 minutes.

If oxygen applied, oxygen saturation goes to 99%

2 minutes after this assessment has been completed (time may vary for individual medic) – the medic is called back to the bedside as the patient has become unresponsive.

New Vital Signs: Heart Rate 56, BP 160/96, RR – 22 but irregular (or shallower)

Eyes: left pupil 6 mm, right pupil 4 mm

If patient given Mannitol

VS: Heart Rate – 90, BP 150/70, RR 22 and regular

Pupils: Go to 4 mm bilaterally

If patient intubated/ and or bagged too vigorously, the patient's heart rate will drop to 40, BP 150/72, No change in unequal pupils.

If patient bagged appropriately – no change in pupils but Vital signs do not deteriorate.

Mild TBI

(Use standardized patient or speak through mannequin, using nurse actor to provide visual cues regarding general appearance and gait.)

Objectives:

The medic will demonstrate:

Elicit/Identify the red flags for TBI

Proper administration of the MACE

Proper triage of the soldier for return to duty or further evaluation

The medic is asked to evaluate a soldier who was 1 vehicle behind a vehicle destroyed by an IED explosion. For this scenario, no information is provided unless the medic specifically asks. (*Note – This case can be changed slightly to include a red flag or gait disturbance that should prompt referral.*)

The soldier is sitting on a stretcher – alert, no apparent injury, a bit anxious

If asked an open-ended question such as “what happened?” the soldier provides the following information: “I was manning the 50 on our Humvee that was about 20 feet behind the lead vehicle that hit an IED. Our Humvee swerved but didn’t go off the road. My CO just wanted me to be checked. I feel fine”.

Red Flag Review

Witnessed LOC – no

2 or more blast exposures in past 72 hours – no

Amnesia/memory loss – no

Unusual behavior/aggression – no

Unequal pupils – no

Seizure – no

Repeated vomiting – no

Double vision – no

Worsening headache – no

Weakness – no

Inability to recognize people, place – no

Unsteady on feet – no

Abnormal speech – no

Other historical information provided if asked:

Had a helmet on, did not hit head

No LOC, dazed initially

No concussion in past 12 months

See MACE attachment for additional findings:

At the end of the case – the medic receives a phone call asking what his recommendation is regarding return to duty/transfer out and why.

Other options:

Was exposed to another explosion 48 hours ago (This is a red flag and should result in transfer out)

Reports feeling unsteady and has ataxia on gait exam

*** For this case we will need contextual information from a medic to make it as realistic as possible.



Military Acute Concussion Evaluation (MACE)

Defense and Veterans Brain Injury Center

Examination: (IX – XIII)

Evaluate each domain. Total possible score is 30.

IX. Orientation: (1 point each)

Month:	0	(1)
Date:	(0)	1
Day of Week:	0	(1)
Year:	0	(1)
Time:	0	(1)

Orientation Total Score 4 /5

X. Immediate Memory:

Read all 5 words and ask the patient to recall them in any order.
Repeat two more times for a total of three trials. (1 point for each correct, total over 3 trials)

List	Trial 1	Trial 2	Trial 3
Elbow	0 (1)	0 (1)	0 (1)
Apple	0 (1)	0 (1)	0 (1)
Carpet	0 (1)	0 (1)	0 (1)
Saddle	(0) 1	0 (1)	0 (1)
Bubble	(0) 1	(0) 1	0 (1)
Trial Score	3	4	5

Immediate Memory Total Score 12 /15

XI. Neurological Screening

As the clinical condition permits, check

Eyes: pupillary response and tracking

Verbal: speech fluency and word finding

Motor: pronator drift, gait/coordination

Record any abnormalities. No points are given for this.

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Military Acute Concussion Evaluation (MACE)

Defense and Veterans Brain Injury Center

XII. Concentration

Reverse Digits: (go to next string length if correct on first trial.
Stop if incorrect on both trials.) 1 pt. for each string length.

4-9-3	6-2-9	0	(1)
3-8-1-4	3-2-7-9	(0)	1
6-2-9-7-1	1-5-2-8-5	(0)	1
7-1-8-4-6-2	5-3-9-1-4-8	(0)	1

Months in reverse order: (1 pt. for entire sequence correct)

Dec-Nov-Oct-Sep-Aug-Jul-Jun-May-Apr-Mar-Feb-Jan

(0) 1

Concentration Total Score 1 /5

XIII. Delayed Recall (1 pt. each)

Ask the patient to recall the 5 words from the earlier memory test
(Do NOT reread the word list.)

Elbow	0	(1)
Apple	0	(1)
Carpet	0	(1)
Saddle	0	(1)
Bubble	(0)	1

Delayed Recall Total Score 4 /5

TOTAL SCORE 21 /30

Notes: _____

Diagnosis: (circle one or write in diagnoses)

No concussion

850.0 Concussion without Loss of Consciousness (LOC)

850.1 Concussion with Loss of Consciousness (LOC)

Other diagnoses _____

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Appendix C

REPORT FORMAT

1. Award No. W81XWH-11-1-0837 2. Report Date _____
3. Reporting period from Sept. 2014 to September 2015
4. PI Dr. Joan Tilghman 5. Telephone No. (410) 951-6157
6. Institution Coppin State University College of Health Professions
7. Project Title Assessment and Evaluation of Traumatic Brain Injuries for Military Health Care Providers

8. Current staff, with percent effort of each on project.

____ % ____ %

9. Award expenditures to date (as applicable):

Personnel \$ 8,075.00 Travel \$ 1,536.20

Fringe Benefits \$401.30 Equipment \$ 1,079.00

Supplies \$30.00 Other \$2,675.00

Subtotal \$ 13,796.50

Indirect Costs \$3,869.92

Fee \$0.00

Total \$ 17,666.42

10. Comments on administrative and logistical matters.

Budget Continues

11. Use additional page(s), as necessary, to describe scientific progress for the quarter in terms of the tasks or objectives listed in the statement of work for this assistance agreement.

12. Use additional page(s) to present a brief statement of plans or milestones for the next quarter.